



**Geoffrey W. Castello**

Kelley Drye & Warren LLP  
One Jefferson Road  
Parsippany, NJ 07054

Tel: (973) 503-5922  
Fax: (973) 503-5950  
gcastello@kelleydrye.com

February 20, 2024

Via ECF

Hon. Louis L. Stanton, U.S.D.J.  
United States District Court  
Southern District of New York  
500 Pearl Street  
New York, NY 10007

**Re:** *FTC, et al. v. Quincy Bioscience Holding Co., Inc., et al.*,  
Case No. 1:17-cv-00124-LLS

Your Honor:

We write on behalf of Defendants Quincy Bioscience Holding Company, Inc., Quincy Bioscience LLC, Prevagen, Inc. d/b/a Sugar River Supplements, Quincy Bioscience Manufacturing, LLC (together, “Quincy”) and Defendant Mark Underwood (“Mr. Underwood” and, together with Quincy, “Defendants”) to resolve an issue that we anticipate will arise at the very outset of the trial concerning the FTC’s Dietary Supplement Guidance (the “Advertising Guide”).

On February 19, 2024—less than two days before trial—Plaintiffs advised Defendants that they intended to remove three key stipulated facts (fact numbers 39, 40, and 41) that had long ago been agreed to by the parties and were filed with this Court eighteen months ago on August 31, 2022. (ECF 299.) Defendants have relied on these facts for the past year and a half in preparing for this trial. Those stipulated facts are as follows:

39. Following the enactment of the Dietary Supplements Health and Education Act of 1994 (“DSHEA”), the FTC issued “Dietary Supplements: An Advertising Guide for Industry” (“Guidance”) “to clarify how long-standing FTC policies and enforcement practices relate to dietary supplement advertising.”

40. The FTC issued the Guidance in 1998.

41. The Guidance is intended to help marketers understand how FTC law applies to the advertising of dietary supplements.

After Defendants objected to the removal of these stipulated facts, Plaintiffs backtracked on removing the stipulated facts, but said that they would “reserve the right to object to any argument or other evidence, including exhibits or testimony, relating to the FTC’s Dietary Supplement Guidance.”

February 20, 2024

Plaintiffs' ever-changing position on the Advertising Guide highlights its relevance to the instant matter. For more than sixteen months, the Advertising Guide was an agreed-upon "joint exhibit" (ECF 299-2, at JX-22). Plaintiffs have since moved to exclude it from evidence and recently removed it from the joint exhibit list. (ECF 343, Motion in Limine 4.) While the Court reserved its decision on the motion to exclude the Advertising Guide (ECF 379), it has already recognized that the "competent and reliable scientific evidence" standard set forth in the Advertising Guide "is a question of fact for expert interpretation." (ECF 331 at 12 (Order on Defendants' Motion for Summary Judgment).)

Moreover, while Plaintiffs argued in their Motion in Limine that certain testimony about the Advertising Guide would constitute impermissible legal opinion (ECF 343 at 11), on the other hand, *Plaintiffs* have quoted directly from the Advertising Guide in their proposed findings of *fact*, not law. (Compare ECF 328, Fact 4 ("Quincy Bioscience LLC did not use procedures generally accepted in the relevant fields to yield accurate and reliable results in conducting the Madison Memory Study") *with* the Advertising Guide ("competent and reliable scientific evidence" requires "procedures generally accepted in the relevant fields to yield accurate and reliable results").) And both Plaintiffs *and this Court* have acknowledged that the question of whether Quincy's claims were supported by "competent and reliable scientific evidence . . . is a question of fact for expert interpretation." (See ECF 331 at 12 (Order on Defs.' Mot. for Summary Judgment).) Without reference to the existence of the Advertising Guide, that question has no factual basis.

To be clear, Defendants do not intend (nor have ever intended) to offer the Advertising Guide as a legal standard. Rather, the Advertising Guide, as the document explains and as is set forth in the parties' stipulated fact 41, presents the "how-tos" for dietary supplement manufacturers to ensure that they have sufficient scientific substantiation for their marketing claims—an operative fact and party admission. Defendants' fact witnesses will testify that they were aware of the Advertising Guide and relied upon it in developing both the scientific substantiation and the marketing claims for Prevagen. Defendants' expert witnesses who have expertise in dietary supplements will testify that they utilize the Advertising Guide in advising dietary supplement companies with respect to the development and substantiation of marketing claims.

Consistent with this anticipated testimony, Defendants intend to reference the Advertising Guide in their opening statement. Defendants wish to address this issue with Your Honor tomorrow before opening statements to avoid any objection or interruption of Defendants' presentation to the jury.

Respectfully submitted,

KELLEY DRYE & WARREN LLP

COZEN O'CONNOR, P.C.

By: /s/ Geoffrey W. Castello

John E. Villafranco (admitted pro hac vice)  
Geoffrey W. Castello  
William A. Escobar  
Jaclyn M. Metzinger  
Glenn T. Graham  
Caitlin R. Hickey

By: /s/ Michael B. de Leeuw

Michael B. de Leeuw  
Tamar S. Wise  
Amanda Giglio  
3 World Trade Center  
175 Greenwich Street  
New York, NY 10007

February 20, 2024

3 World Trade Center  
175 Greenwich Street  
New York, NY 10007  
Tel: (212) 808-7800  
Fax: (212) 808-7897  
jvillafranco@kelleydrye.com  
gcastello@kelleydrye.com  
jmetzinger@kelleydrye.com  
ggraham@kelleydrye.com  
chickey@kelleydrye.com

Tel: (212) 908-1331  
mdeleeuw@cozen.com  
twise@cozen.com  
agiglio@cozen.com

*Counsel for Defendant Mark Underwood*

*Counsel for Defendants Quincy Bioscience  
Holding Company, Inc., Quincy Bioscience,  
LLC, Prevagen, Inc. d/b/a Sugar River  
Supplements, and Quincy Bioscience  
Manufacturing, LLC*